

SUPPORTING STATEMENT
Record Retention Requirements
for the Soy Protein/CHD Health Claim
0910-0428

A. JUSTIFICATION

1. Necessity of the Information Collection

The Federal Food, Drug, and Cosmetic Act (the act) was amended by the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) which strengthened the Secretary's legal authority (and, by delegation, that of the Food and Drug Administration (FDA)) to require nutrition labeling on foods and by defining circumstances under which claims may be made about nutrients in foods. The 1990 amendments added section 403(r) (21 U.S.C. 343(r)) to the act (Tab A). Among other things section 403(r) provides that a health claim may be used on the label of a food only if the claim is made in accordance with a regulation issued by FDA.

The FDA has proposed in the Federal Register of November 10, 1998 (63 CFR 62977) (Tab B), to establish a regulation concerning the relationship between soy protein and coronary heart disease (CHD) (proposed § 101.82 (21 CFR 101.82)). In this document, FDA is proposing to require that a manufacturer of a food product bearing the proposed health claim for soy protein/CHD whose product contains non-soy sources of protein retain all the records that permit the calculation of the ratio of soy protein to other sources of protein in the food. The manufacturer of such a food product would be required to make those records available for review and copying by appropriate regulatory officials

upon request and during site visits.

We request OMB approval for the following new information collection requirements contained in § 101.85:

21 CFR 101.85 Record Retention and Review

Would require food manufacturers to retain, and make available to regulatory officials, records concerning the ratio of soy protein to other sources of protein in a food product bearing a soy protein/CHD health claim.

2. How, by Whom, and for What Purpose Information is Used

The information would be used by FDA during inspection review of firms' label claims to determine the basis of soy protein/CHD health claims. The proposed provisions would require that firms maintain, and make available to regulatory officials, all available records that permit calculation of the ratio of soy protein to other sources of protein in a food when that food bears a soy protein/CHD health claim. The agency believes that requiring records retention in this circumstance for soy protein/CHD health claims is necessary for the efficient enforcement of the act. Without access to this information, FDA would be unable to ensure that food products that contain non-soy proteins comply with the requirements for the soy protein/CHD health claim.

3. Use of Improved Information Technology

The proposed regulation does not specifically prescribe the use of automated, electronic, mechanical, or other technological techniques or other forms of information technology as necessary for

use by firms. Companies are free to use whatever forms of information technology may best assist them in retaining the appropriate records and making them available to regulatory officials.

4. Identification of Duplication and Similar Information Already Available

No duplication of Federal regulations concerning the proposed regulation for a health claim for soy protein is likely because of the clear Congressional authorization that FDA promulgate regulations pertaining to health claims for foods as opposed to the jurisdiction of the U.S. Department of Agriculture (meats and poultry) and the Federal Trade Commission (advertising).

5. Small Business

The proposed notification procedures are no more burdensome for small businesses than for large. The proposed requirements are the minimum requirements for the proposed health claim for soy protein and CHD.

6. Consequences if Data Were Collected Less Frequently

There are no consequences to Federal program or policy activities if the information is not collected or is collected less frequently. Under the proposed regulations, a food manufacturer could not use a soy protein/CHD health claim on a food product containing non-soy sources of protein if it did not retain the appropriate records for possible review by regulatory officials.

7. Special Circumstances

Not applicable.

8. Outside Consultation

Publication of this proposal will provide an opportunity for persons outside the agency to offer their comments on the proposed record retention requirements associated with the soy protein/CHD health claim.

9. Gifts

This information collection does not provide for payment or gifts to respondents.

10. Confidentiality

Information that is trade secret or confidential is subject to FDA's regulations on the release of information, 21 CFR Part 20.

11. Sensitive Questions

This information collection does not involve any questions of a sensitive nature.

12. Respondent Hour Burden and Annualized Burden Hour Costs Estimates

Burden Hours

FDA estimates the total hour burden for this information collection to be 25 hours, as follows:

ESTIMATED ANNUAL RECORDKEEPING BURDEN

21 CFR Section	No. Of Respondents	Annual Frequency per Response	Total Annual Responses	Hours per Response	Total Hours
101.82(c)(ii)(B)	25	1	25	1	25

There are no capital costs or operating and maintenance costs associated with this collection of information.

Based upon its experience with the use of health claims, FDA estimates that only about 25 firms would be likely to market products bearing a soy protein/CHD health claim and that only, perhaps, one of each firm's products might contain non-soy sources of protein along with soy protein. The records that would be required to be retained by proposed § 101.82(c)(ii)(B)(2) are the records, e.g., the formulation or recipe, that a manufacturer has and maintains as a normal course of its doing business. Thus, the burden to the food manufacturer would be that involved in assembling and providing the records to appropriate regulatory officials for review or copying.

Estimated Annualized Cost for the Burden Hours

FDA estimates that the cost for the retention and disclosure of records for food products under this proposed regulation would equal approximately \$1300; or the total time of 25 hours x \$26/hour (salary) + \$650 in overhead = a Total cost of \$1300. In this calculation of cost, FDA estimates that the average hourly cost for retaining the records and making them available to regulatory officials would be equivalent to that of a GS-13 base salary of \$26. Overhead is estimated as being equal to salary.

13. Annual Cost Burden to Respondent

FDA believes that the proposed requirements would not result in a cost burden, other than the hour burden, to respondents. The information that a firm would be required to retain and make

available is the information that the firm would use as a basis for a soy protein/CHD health claim on its products. Thus, these are costs that would be incurred by a firm as a normal cost of doing business and are, therefore, not associated with this collection.

14. Annualized Cost to the Federal Government

FDA's review of the retained records would generally occur as part of its scheduled inspection of a food firm. FDA has estimated the annualized cost to the Federal Government for the review of records retained by firms as support for soy protein/CHD claims under proposed 101.82(c)(ii)(B)(2), based on the estimated number of products for which records would be retained, as follows:

Estimated number of hours per year = $25 \times 1 = 25$ hours; or

Estimated number of products = 25

Estimated number of hours for the review and evaluation of the records = 25

Estimated cost for review and evaluation = \$1100

Total time of 25 hours x \$22/hour

for review and evaluation (salary) = \$550

Overhead = \$550

Total cost (Salary + Overhead) = \$1100

Hourly cost for review and evaluation of the cost to the Federal government is estimated as being equivalent to that of a base GS-12 salary. Overhead is estimated as being equal to salary.

15. Changes of Adjustments in Burden

The increase in the hour burden is due to the proposed establishment of a new recordkeeping requirement.

16. Statistical Analysis, Publication Plans, and Schedule

Not Applicable

17. Approval Not to Display Expiration Date

There are no reasons why display of the expiration date for OMB approval of the information collection would be inappropriate.

18. Exceptions to the Certification Statement Identified in Item 19

No exceptions to the certification statement identified in Item 19 of the instructions for completing OMB Form 83-I have been identified.

B. COLLECTIONS OF INFORMATION EMPLOYING STATISTICAL METHODS

There are no plans to publish the information collected under the provisions of this proposed regulation for statistical use. The collection of information required under the provisions of this proposed regulation do not employ statistical methods.